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March 18, 1999

Dockets Management Branch (HFA-305)
Docket No. 98N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 02857

Dear Sir or Madam:

It is my understanding the Docket No. 98N-1265 would limit the interstate shipment of compounded prescription medications. This is not a good idea. Many patients can only obtain their prescriptions from specialized sources. My daughter has celiac disease. Celiac disease is a gluten intolerance. Gluten is found in products made or derived from wheat, barley, rye and oats. The ingestion of any amount of gluten will cause the celiac patient to become ill.

Most pills contain wheat or other grain based products. Gluten is not one of the active ingredients but it is necessary to form the pill. Stokes Pharmacy in New Jersey specializes in providing gluten-free medications. Many celiac patients order medications from Stokes because this their only source for gluten-free medications. Without a pharmacy like Stokes celiac patients may forego medication due to the risk of gastrointestinal damage from gluten. If interstate shipment of medications were prohibited then celiac patients would suffer.

While my experience is limited to celiac disease I am sure there are other food allergies and conditions which require specialized medications. I am also sure that there are other pharmacies like Stokes that fulfill special medication needs.

Thank you for your consideration of the needs of celiacs when you review Docket No. 98N-1265. Please do not approve Docket No. 98N-1265.

Sincerely,


Francie Kelley

98N-1265

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